UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,020	06/28/2005	Kenji Fujii	Q88147	4034

23373 7590 03/25/2010

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
03/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/541,020	FUJII ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009 and 20 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-30 and 37-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-30 and 37-39* is/are rejected.

7)☒ Claim(s) *39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-30 and 37-39 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and request for suspension filed October 19, 2009, was received and entered into the present application. Accordingly, prosecution has been reopened following the requested suspension period of three months.

Applicant's additional submission dated January 20, 2010 has been received and entered into the present application. Applicant's amendment to the specification dated October 19, 2009 has been noted.

Claims 28-30 and 37-39 are pending and under examination. Claim 39 is newly added. Claims 31-36 are cancelled. Claims 28-30 are amended.

Applicant's arguments, filed October 19, 2009 and January 20, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claim 39 is objected to for failing to conclude with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 30 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 28 specifies that the fatigue reducing agent to be administered comprises reduced coenzyme Q of the formula (1) and oxidized coenzyme Q of the formula (2), wherein the ratio of reduced coenzyme Q to the total coenzyme Q is 60-100% by weight.

In particular, it is unclear how the ratio of reduced coenzyme Q to the total amount of coenzyme Q can be 100% by weight if the fatigue reducing agent is expressly defined as comprising both a reduced form of coenzyme Q *and* an oxidized form of coenzyme Q. The claim explicitly requires that the agent comprise both reduced and oxidized coenzyme Q, wherein the reduced form of coenzyme Q is found in a ratio of 60-100% by weight to the total amount of coenzyme Q, which is equivalent to a ratio of 60:100 to 100:100 (if the percentage is read as "per hundred"). However, such a ratio would encompass an embodiment wherein the total amount of coenzyme Q was comprised of 100% reduced coenzyme Q, i.e., wherein the total coenzyme Q did not contain any oxidized coenzyme Q. This clearly conflicts with the body of the claim that explicitly requires both a reduced coenzyme Q and an oxidized coenzyme Q. As a result of this ambiguity in the claim, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the subject matter for which Applicant is presently seeking protection. Clarification is required.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

For the purposes of examination, the claims will be interpreted to require that both reduced coenzyme Q and oxidized coenzyme Q are present in the composition to be administered (i.e., not just reduced coenzyme Q alone if the ratio of reduced coenzyme Q to total coenzyme Q was 100%).

Claims 28, 30 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 28 specifies that the fatigue reducing agent to be administered comprises reduced coenzyme Q of the formula (1) and oxidized coenzyme Q of the formula (2), wherein the ratio of reduced coenzyme Q to the total coenzyme Q is 60-100% by weight.

In particular, there is insufficient antecedent basis for the term “the ratio” or the term “the total coenzyme Q” as recited in instant claim 28, because the preceding text of the claim fails to provide any reference to "a ratio" or "total coenzyme Q" *per se*.

For this reason, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Present claim 28 specifies that the fatigue to be reduced via the instantly claimed method is physical exhaustion. Present claim 37 specifies that the fatigue is muscle fatigue.

In particular, it is unclear how instant claim 37 is intended to further limit instant claim 28, which specifies that the fatigue to be reduced is physical exhaustion. Independent claim 28 clearly specifies that the fatigue to be treated is physical exhaustion and the dependent limitation of instant claim 37 to then specify that the fatigue is muscle fatigue does not further narrow the scope of subject matter circumscribed by instant claim 28. Accordingly, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the subject matter for which Applicant is presently seeking protection. Clarification is requested.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

Claim Rejections - 35 USC § 103

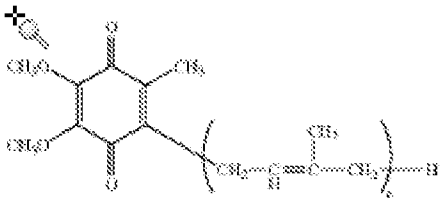
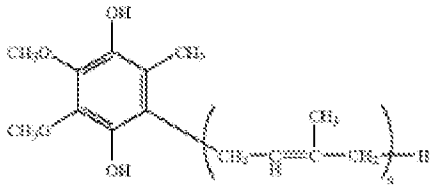
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-30 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujii et al. (WO 2002/092067; 2002), citing to U.S. Patent Application Publication No. 2004/0115181 (2004) for an English translation, in view of Wilson et al. ("Exertional Fatigue Due to Skeletal Muscle Dysfunction in Patients with Heart Failure", *Circulation*, 1993; 87:470-475), further in view of Remington's Pharmaceutical Sciences (Fifteenth Edition, 1980; p.712), each already of record, for the reasons of record set forth at p.3-8 of the previous Office Action dated May 18, 2009, of which said reasons are herein incorporated by reference.

Newly amended claim 28 and newly added claim 39 are properly included in the present rejection because Fujii et al. teaches a composition for transmucosal administration comprising an oxidized

coenzyme Q of the formula  , wherein n represents an integer of 1 to 12, and/or reduced coenzyme Q of the formula  , wherein n also represents an integer or 1 to 12 (p.1, para.[0007-0009]), wherein coenzyme Q with 10 side chain repeating units (i.e., an oxidized coenzyme Q10 and reduced coenzyme Q10) are preferably used (p.2, para.[0016]), wherein the total content of the above oxidized and reduced coenzyme Q amounts to 0.0001-99% by weight of the total composition (p.1, para.[0010]). Fujii et al. further teaches a method for treating, *inter alia*, cerebral infarction, heart failure, etc. (p.2, para.[0023]) comprising applying the composition for transmucosal administration to human or animal mucosa with a disease (p.5, col.18), such as, *inter alia*, to the oral mucosa (i.e., "orally" as in instant claim 38; p.1, para.[0011]), using, for example, an oral mucosal applicator, toothpaste or drop (p.2, para.[0019]), wherein the composition may be used in humans, including aged persons (p.4, para.[0042]), dogs, cats, race horses, cows, horses, pigs, rabbits, rats, mice, birds and the like (p.1, para.[0010]).

The teachings of wherein the total content of the above oxidized and reduced coenzyme Q amounts to 0.0001-99% by weight of the total composition (i.e., which is understood to mean that each of the oxidized and reduced coenzyme Q components can be present in an amount of 0.001-99% by weight of the total composition; p.1, para.[0010]) by Fujii et al. renders the presently claimed range of (1) the ratio of reduced coenzyme Q to the total coenzyme Q to be 60-100% by weight (claim 28) or (2) the ratio of reduced coenzyme Q to the total coenzyme Q to be 80-99.5% by weight (claim 39) *prima facie*

obvious to one of ordinary skill in the art at the time of the invention. In particular, an express teaching that each of the oxidized or reduced coenzyme Q components are present in an amount of 0.0001-99% by weight of the total composition clearly overlaps with those ranges specifically recited in the present claims. As stated in the MPEP at §2144.05, "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)…"[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). See also *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005)."

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the Examples of the present specification show unexpected results to overcome the rejection of the claims. Applicant refers to Ex.1, stating that Table 1 shows that the results for the reduced coenzyme Q group were statistically significant compared to the control group and demonstrated a "significant increase" in the level of coenzyme Q in muscle that was not seen with the administration of oxidized coenzyme Q10. Applicant also refers to Ex.2, stating that the level of total (reduced) coenzyme Q10 in muscle decreased by the administration of oxidized coenzyme Q10 as compared to a significant increase in the total (reduced) coenzyme Q10 in muscle by the administration of reduced coenzyme Q10, which Applicant alleges is unexpected because oxidized coenzyme Q is "conventionally known" to be reduced to reduced coenzyme Q in the body. Applicant also refers to Ex.3, stating that he is "not relying on Example 3 to show that the results in Example 3 were unexpected" (p.5, Remarks). Applicant states that Ex.3 provides a comparison with Ex.4 to show that oxidized and reduced coenzyme Q had a significant prolongation effect on maximum running time in young rats (Ex.3) such that the artisan would have expected that the action of reduced coenzyme Q in

aged rats would be the same as oxidized coenzyme Q in aged rats. Applicant goes on to state that, however, Ex.4 shows that reduced coenzyme Q had a significant prolongation effect on the maximum running time of aged rats, but that oxidized coenzyme Q showed no or only a slight prolongation effect on maximum running time in aged rats.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant urges the allegedly unexpected results provided in Ex.1-4 of the instant specification, stating that these unexpected results are sufficient to overcome the instant rejection under 103(a). These results, however, fail to establish an unexpected effect commensurate in scope with the instantly claimed subject matter because: (1) Ex.1 and Comparative Ex.1 are directed to the levels of coenzyme Q in the muscle following administration of either reduced or oxidized coenzyme Q10 as compared to the control group; (2) Ex.2 and Comparative Ex.2 are directed to the levels of reduced coenzyme Q in the muscle following administration of either reduced or oxidized coenzyme Q10 as compared to the control group; (3) Ex.3 and Comparative Ex.3 are directed to the prolongation of maximum running time in young rats treated with reduced coenzyme Q10 (which contained about 1% of oxidized coenzyme Q10) or oxidized coenzyme Q10; and (4) Ex.4 and Comparative Ex.4 are directed to the prolongation of maximum running time in aged rats treated with reduced coenzyme Q10 (which contained about 1% of oxidized coenzyme Q10) or oxidized coenzyme Q10. Given that the instant claims are directed to the use of fatigue reducing agent that comprises a reduced coenzyme Q of formula (1) *in combination with* an oxidized coenzyme Q of formula (2) in a ratio of reduced coenzyme Q to total coenzyme Q of 60-100% by weight, the results presented in Ex.1, Comparative Ex.1, Ex.2 and Comparative Ex.2 are clearly not germane to establishing an unexpected effect of the instantly claimed combination because Ex.1, Comparative Ex.1, Ex.2 and Comparative Ex.2 only tested the effect of each component individually (i.e., reduced coenzyme Q10 versus oxidized coenzyme Q10) and failed to determine the effect of the two components in combination as instantly claimed. Accordingly, the

proffered results of Ex.1, Comparative Ex.1, Ex.2 and Comparative Ex.2 are clearly not commensurate in scope with what is presently claimed and, therefore, are unpersuasive in establishing nonobviousness of the instant claims.

With regard to the data provided in Ex. 3, Comparative Ex.3, Ex.4 and Comparative Ex.4, Applicant urges these data as unexpected results, but, again, the data fails to be commensurate in scope with the instantly claimed subject matter. In particular, Applicant relies upon the data provided in Ex.4 and Comparative Ex.4 as evidence of unexpected results (by Applicant's own admission at p.5, the results of Ex.3 were not relied upon by Applicants to demonstrate an unexpected result but were used as a comparison). However, the results of Ex.4 and Comparative Ex.4 are restricted to the use of either (a) reduced coenzyme Q10 with 1% oxidized coenzyme Q10 or (b) oxidized coenzyme Q10 on aged rats to determine the effect on maximum running time. Though it is noted that a statistically significant increase was demonstrated on maximum running time in aged rats treated with the 300 mg/kg reduced coenzyme Q10 + 1% oxidized coenzyme Q10 combination in soybean oil (see, e.g., Table 4 at p.22 of the instant specification) as compared to the control group (which received soybean oil alone) or the 300 mg/kg oxidized coenzyme Q10 group, the instant claims are directed to the use of a combination of reduced coenzyme $Q_{1\text{-}12}$ with oxidized coenzyme $Q_{1\text{-}12}$, wherein the amount of reduced coenzyme Q to total coenzyme Q ranges from 60-100% by weight.

These proffered results, however, do not provide a basis for concluding that the full scope of the claimed subject matter would not have been obvious because the results are limited to a very specific combination (i.e., 300 mg/kg reduced coenzyme Q10 + 1% oxidized coenzyme Q10 in soybean oil), while the instant claims subject to this rejection encompass the use of the combination of a reduced coenzyme $Q_{1\text{-}12}$ with oxidized coenzyme $Q_{1\text{-}12}$, wherein the amount of reduced coenzyme Q to the total amount of coenzyme Q ranges from 60-100% by weight. Further, it has not been argued or demonstrated on the record that the results obtained with the exemplified combination(s) of *reduced coenzyme* Q_{10} in an

amount of 300 mg/kg with 1% *oxidized coenzyme* Q_{10} in soybean oil would have been exemplary of the same or substantially similar results that would have been expected to occur over the wide range of possible reduced coenzyme Q forms and/or possible oxidized coenzyme Q forms and/or the wide range of therapeutic amounts of each of the reduced and/or oxidized coenzyme Q components of the claimed agent.

In this regard, MPEP §2144.08(II)(B) is relied upon and reads, in-part: "When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the Applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. Id. For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a *prima facie* case of obviousness if a skilled artisan 'could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.' *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (**Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.**) But see, *In re Grasselli*, 713 F.2d at 743, 218 USPQ at 778 (Evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with 'an alkali metal' where it was well known in the catalyst art that different alkali metals were not interchangeable and Applicant had shown unexpected results only for sodium containing materials); *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (Evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972)

(one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way)." (emphasis added)

Here, even though the results shown with the 300 mg/kg reduced coenzyme Q_{10} plus 1% oxidized coenzyme Q_{10} in soybean oil formulation demonstrated a statistically significant effect in prolonging maximum running time (i.e., reducing fatigue) in aged rats treated with the formulation that appears to be both unexpected and unpredictable from the prior art, just as a single point in space fails to define a line, the results demonstrated for this discrete combination is insufficient to establish the non-obviousness of the entirety of the presently claimed subject matter [i.e., any reduced coenzyme Q_{1-12} in combination with any oxidized coenzyme Q_{1-12} in amounts wherein the ratio of reduced coenzyme Q to total coenzyme Q ranges from 60-100% by weight] absent any concrete evidence or scientifically sound reasoning as to why (1) the other claimed forms of reduced coenzyme Q in combination with the other claimed forms of oxidized coenzyme Q or (2) any other amounts of the claimed reduced and/or oxidized coenzyme Q would have been reasonably expected to demonstrate the same apparently unexpected effect in reducing fatigue in an aged animal.

Accordingly, while Applicant's remarks and data provided in Ex.1-4 of the instant specification have been fully and carefully considered, it remains that Applicant has not provided sufficient evidence and/or explanation to support the allegation that an apparently unexpected effect in reducing fatigue in an aged animal using the combination of 300 mg/kg reduced coenzyme Q_{10} plus 1% oxidized coenzyme Q_{10} in soybean oil formulation has been demonstrated over the full scope of the claimed subject matter. Furthermore, Applicant has failed to provide any objective evidence, scientific reasoning or persuasive argument on the record to provide an adequate basis for concluding that the discrete combination exemplified is probative of the same (or at least substantially similar) effect over the entire scope of the claimed invention. In short, the evidence is, respectfully, insufficient to be supportive of nonobviousness on the basis of an unexpected result over the full scope of the claimed subject matter because the

proffered data is not commensurate in scope with the claimed subject matter.

Applicant is again reminded that, should he rely upon unexpected results to patentably distinguish over the prior art, the present claimed must be limited to the embodiment(s) which is (are), in fact, unexpected. Note also that Applicant is burdened with the responsibility of explaining why the evidence provided to support secondary considerations is probative of non-obviousness beyond what data is explicitly provided as unexpected. Please see MPEP §716.02(b)[R-2], particularly Section (II), which states, "[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness." *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992). In the instant case, though the instant data was provided in the instant specification and not a declaration, the burden is nonetheless on Applicant to explain the data provided as evidence of non-obviousness of the claimed subject matter.

In view of the reasons provided *supra*, the evidence supporting the obviousness of the instantly claimed invention outweighs the remarks and evidence provided to support the non-obviousness of the instantly claimed invention. Therefore, the rejection stands.

For these reasons *supra*, and those previously made of record at p.3-8 of the Office Action dated May 18, 2009, rejection of claims 28-30 and 38-39 is proper.

Double Patenting (New Grounds of Rejection)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28, 30 and 37-39 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent Application No. 11/993,743.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the cited patents are not considered patentably distinct from each other because the pending claims are rendered obvious by the copending claims.

The copending claims provide for a method of treating fatigue (which is understood to be synonymous with "physical exhaustion" as recited in the instant claims) in a mammal comprising administering an effective amount of a composition comprising a reduced coenzyme Q of a formula identical to that claimed as instant formula (1) in combination with an oxidized coenzyme Q of a formula identical to that claimed as instant formula (2) and lipoic acid or a derivative thereof. Though the instant claims are directed to the administration of the claimed coenzyme Q formulation to "middle aged or older persons", the copending claims broadly teach the use of the disclosed coenzyme Q formulation for use in patients or persons *per se* and, thus, places the treatment of any human at any stage of development (i.e., "young", "middle aged" or "older") within the possession of the public, absent factual evidence to the contrary.

The copending claims fail to explicitly disclose the amounts of reduced coenzyme Q to the total amount of coenzyme Q (claims 28 and 39) or the administration of the composition orally (claim 38).

Regarding the presently claimed ratios of reduced coenzyme Q to total coenzyme Q of the composition (i.e., 60-100% by weight or 80-99.5% by weight), the determination of the optimal ratio of reduced coenzyme Q to total coenzyme Q (i.e., which includes both the reduced and oxidized forms of

coenzyme Q) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease to be treated, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound(s) are administered as part of a drug combination. Thus, the amounts (and, thus, the ratios) that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific ratios are not seen to be inconsistent with the amounts and ratios that would have been easily and routinely determined by the skilled artisan.

Additionally, it is noted that the skilled artisan would have considered the amount of the active agents to be administered, the tolerability to the regimen (i.e., toxicological or adverse effect), the medical condition to be treated, and patient compliance with the regimen to determine the optimum route of administration (i.e., oral, transdermal, subcutaneous injection, etc.). Please see Jacob, *Pharmacology*, at p.1-3, especially p.3, which teaches various route of administration well known in the art at the time of the invention, the use of any of which would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention for these reasons *supra* and absent factual evidence to the contrary.

Accordingly, rejection of claims 28, 30 and 37-39 is proper over claim 9 of U.S. Patent Application No. 11/993,743 as claiming obvious and unpatentable variants. This is a provisional rejection because the claims have not, in fact, yet been patented.

Conclusion

Rejection of claims 28-30 and 37-39 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

March 21, 2010